UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/801,830	03/17/2004	Jacques Chevallet	02508.0103	5171

22852 7590 10/23/2006

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP
901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

EXAMINER	
KIM, SUN U	

ART UNIT	PAPER NUMBER
1723	

DATE MAILED: 10/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/801,830	CHEVALLET ET AL.	
	Examiner	Art Unit	
	John Kim	1723	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 August 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-3, 5-6, 20-21, 23, 25-26 and 35-36 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 96/28198 (hereinafter referred to as WO '198). WO '198 teaches a device for the extracorporeal treatment of blood comprising first filter (10) and a second filter (13) comprising membranes inherently separating chambers into a first chamber and a second chamber and a first inlet of the first chamber of the first filter (10) connected to a blood input line (22) and a first outlet of the first chamber of the first filter (10) connected to a blood output line (23) and a second outlet of the second chamber of the first filter (10) connected to the first inlet of the second chamber of the second filter (13) via a line, the first outlet of the first chamber of the second filter (13) connected to the input line (22) via a line, the second outlet of the second chamber of the second filter (13) has a discharge line (see figure 2; page 4)(claims 1-3). Regarding claims 5-6, WO '198 teaches that the first filter has membrane pore size of 0.1 to 2 micrometers and the second filter has membrane pore size of 0.02 to 0.08 micrometers wherein the first filter membrane is inherently high-flow membrane and permeability of the first membrane is greater than the second filter membrane by sheer pore size difference (see page 4, lines 1-13). Regarding claims 20-21, WO '198 teaches a reactor (15) containing gel beads (14) with immobilized CD4 receptor to collect or adsorb HIV particles (see figure 2; page 4). Regarding claims 23 and 25-26, WO '198 teaches a pump (21) on an input line (22) upstream of the connection point connecting the input line (22) to a line connecting the first outlet of the

second filter (13) and the first inlet of the first filter (10) and a pump (16) on a line connecting the second outlet of the first filter (10) and the first inlet of the second filter (13) (see figure 2). Regarding claims 35-36, WO '198 teaches the method of filtering blood through the first filter (10) to produce first filtrate (11), filtering the first filtrate (11) through the second filter (13) to produce second filtrate (18) and sending the second filtrate (18) to the input line (22) and sending blood out from the first filter (10) to the output line (23) and sending a retentate (12) to a drain line wherein the membrane of the second filter (13) has smaller pore size than the membrane of the first filter to remove molecules of molecular weight less than the molecular weight of the molecules filtered by the membrane of the first filter (10) (see page 4).

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 4, 11-15 and 27-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO '198 as applied to claim 1 above, and further in view of US Pat. No. 5,679,245 (hereinafter referred to as Manica). WO '198 teaches a device for the extracorporeal treatment of blood as described in above paragraph 5. Structural elements claimed in claims 4, 11-15 and 27-34 are well-known in the art of extracorporeal blood treatment as described by Manica. Manica teaches an extracorporeal blood treatment device comprising a waste liquid collection container (86) on a balance (92) and connected to an outlet of a blood treatment unit (44) with a pump (84)(see col. 6, lines 3-20)(claims 4, 28, 30, 31-34) and post-dilution line connected to a replacement fluid container (68) containing source of sterile liquid on a balance (92) at one end

and connected to blood output line at the other end with a pump (66) on the post-dilution line (claims 11, 27, 30, 31, 32-34) and suggested connection of post-dilution line to a pre-dilution line to the input line with a pump (claims 12-15, 29)(see col. 5, lines 31-45) and a control computer (102) and monitor computer (104) work together to monitor the weight of replacement fluid and waste liquid by receiving weight signals from the balances (92) and control corresponding pumps (66, 84) (claim 34) (see figures 2-3b; col. 8, line 7 – col. 9, line 31). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to incorporate claimed structures well-known in the art to accurately balance the fluid in the extracorporeal treatment of blood as suggested by Manica.

5. Claims 7-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO '198 as applied to claim 1 above, and further in view of Journal of Membrane Science, 44 (1989), pages 89-114 (hereinafter referred to as Shettigar article). WO '198 teaches a device for the extracorporeal treatment of blood as described in above paragraph 5. WO '198 teaches that the first membrane pore size is greater than the second membrane pore size (see page 4). Claims 7-9 essentially differ from the apparatus of WO '198 in reciting that the ratio of the cut-off value of the first membrane i.e. the membrane of the exchanger to the cut-off value of the second membrane i.e. the membrane of the treatment unit is less than or equal to 3 (claim 7), the difference in the cut-off value between the first membrane and the second membrane lies between 20,000 dalton and 30,000 dalton (claim 8), the cut-off value of the first membrane is less than or equal to 40,000 dalton (claim 9) and the cut-off value of the second membrane is less than or equal to 10,000 dalton (claim 10). Shettigar article teaches an apparatus comprising two filters in series wherein the first filter has cut-off value of 40,000 daltons and the second filter

has cut-off value of 10,000 daltons such that it removes uremic solutes between 10,000 and 40,000 daltons (see , figure 5; page 94). It would have been an obvious matter of design choice to have claimed ratio of the cut-off value or claimed difference in the cut-off value between the first membrane and the second membrane, since applicant has not disclosed that such ratio or difference solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with the first membrane having the cut-off value of 40,000 daltons and the second membrane having the cut-off value of 10,000 daltons as suggested by Shettigar article to remove uremic solutes.

6. Claims 16-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO '198 as applied to claim 1 above, and further in view of US Pat. No. 5,536,412 (hereinafter referred to as Ash). WO '198 teaches a device for the extracorporeal treatment of blood as described in above paragraph 5. Claims 16-17 essentially differ from the apparatus of WO '198 in reciting a plasma filter having a cut-off value between 1 million and 5 million daltons. Ash teaches an extracorporeal blood treatment device comprising a plasma filter having cut off value of 50,000 to 6 million daltons wherein its membrane allows albumin or middle molecular weight molecules to transmit selectively over larger molecules to provide removal of toxins (see col. 6, lines 21-47). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to substitute a plasma filter for the first filter of WO '198 for effective removal of larger molecules such as toxins as suggested by Ash. Regarding claims 18-19, Ash suggests that albumins or middle molecular weight molecules are important for blood functions such that these molecules need to pass through the membrane and back into the blood (see col. 6, lines 39-43). It would have been obvious to a person of ordinary skill in the art at the time the invention was

made to have the second filter having smaller membrane pore size than the first filter as taught in WO '198 but large enough to remove smaller size toxins but allow albumins to pass through the membrane to be returned to the blood to minimize potential interference with other blood functions.

7. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO '198 as applied to claim 1 above, and further in view of US Pat. Application Publication No. 2005/0043666 A1 (hereinafter referred to as Pan). WO '198 teaches a device for the extracorporeal treatment of blood as described in above paragraph 5. Claim 22 essentially differs from the apparatus of WO '198 in reciting a radiation device active on the first duct. WO '198 teaches the reactor (15) with gel beads with immobilized CD4 receptor to remove HIV particles (see figure 2; page 4). Pan teaches an extracorporeal blood treatment device comprising a UV lamp (24) radiating a tube containing blood to kill HIV virus (see abstract; figure 3; paragraph 0035-0039). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include UV lamp in the first duct in the apparatus of WO '198 to effectively kill HIV virus as suggested by Pan.

8. Applicant's arguments filed 8/16/06 have been fully considered but they are not persuasive. Applicants argue that WO '198 does not teach a second chamber having a waste liquid discharge line" or "sending a non-filtered liquid from the second chamber of the treatment unit to a waste drain line". However, a tubing or a line connected to the outlet of the second chamber of the second filter (13) of WO '198 is the waste liquid discharge line. A waste liquid discharge line of the second chamber is interpreted as a line carrying a waste liquid from the

outlet of the second chamber. The waste liquid discharge line is not given a meaning to a line connected to a drain or a waste liquid container as applicant might be intending to claim.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Kim whose telephone number is 571-272-1142. The examiner can normally be reached on Monday-Friday 7 a.m. - 3:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Kim can be reached on 571-272-1142. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

John Kim
Primary Examiner
Art Unit 1723

JK
October 19, 2006